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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,285

11/13/2003

Wamis Singhatat

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GENE WARZECHA
LINVATEC CORPORATION
11311 CONCEPT BOULEVARD
LARGO, FL 33773

EXAMINER

DORNBUSCH, DIANNE

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,285	Applicant(s) SINGHATAT, WAMIS	
	Examiner DIANNE DORNBUSCH	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-12,15,19,21,22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-12, 15, 19, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation in claim 8, states that the locking mechanism is integrally formed with the proximal body, is considered new matter since the original disclosure does not state that this components are integrally formed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 15, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (US 6,293,961).

Schwartz discloses a distal body portion (20, distal portion), a proximal body portion (24) with opposed gripping portions (36 and 37) defining a suture receiving aperture (30) transverse to the longitudinal axis, a channel (22), the anchoring member includes an annular ring (distal most portion of 20 is an annular ring), a locking mechanism (36 and 37 portions that lock into each other, also disclosed are multiple teeth and grooves, one set could be the gripping portions and another set the locking mechanism), and in the open position the proximal portion is non-circular and is circular in the closed position (Fig. 9). The locking mechanism contains a male/female engagement mechanism (Fig. 9). The suture anchor is bioabsorbable (Col. 2 Lines 25-31). The suture has two ends and the second end is receivable in the aperture in the open position. A loop is formed as seen in Fig. 1.

With respect to the "adapted to" statement, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 and 6-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (2003/0088272). In view of Schwartz et al. (US 6,293,961).

Claim 1:

Smith discloses a suture anchor for insertion into a body tissue cylindrical bone hole to anchor a suture to the body tissue bone (Fig. 1 and [0003]), the suture anchor (16, 18) comprising: a distal body portion (15) defining a longitudinal axis (Fig. 2), the distal body portion having a diameter sufficient to fit in said bone hole (Fig. 1), being insertable into the body tissue bone hole and defining a radially outwardly projecting anchoring member (distal portion of 2) operable to retain the suture anchor in the body tissue bone hole (Fig. 1 and [0049]); and a proximal body portion (26) integrally formed with and extending longitudinally from the distal body portion (Fig. 2 where it extends by legs 31 and 33), the proximal body portion having opposed gripping portions (40, 50) ([0050] first sentence, [0052]), and Fig. 2) moveable transversely between an open position (Fig. 2C) and a closed position (Fig. 1), the gripping portions defining a transverse suture receiving aperture (combination of 35 and 60) between them for receiving at least one transversely oriented suture (a portion of the suture is oriented transversely as seen in Fig. 2D, in addition the device is capable of holding a transverse

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suture directly at the gripping portion), the aperture being relatively larger and able to receive the suture (10) in two-way, free sliding relationship when the gripping portions are in the open position (Fig. 2) and the aperture being relatively smaller and able to grip the suture in gripping relationship when the gripping portions are in the closed position ([0052]-[0053] and [0056]), the proximal body portion being responsive to insertion into the bone hole (Fig. 1 and [0055]) to move the gripping portions from the open to the closed position as the suture anchor is pushed into the bone hole (Fig. 1 and [0055]-[0056]), wherein the proximal body portion has a maximum transverse dimension in the open position (Fig. 2C), the proximal body portion has a smaller maximum transverse position in the closed position (Fig. 1 since the legs (31 and 33) are compressed inside the bone), and the anchoring member has a maximum transverse dimension smaller than the maximum transverse dimension of the proximal body portion in the open position (Fig. 1 and 2 where the proximal body portion ends at point 4 which is larger than 2).

The examiner would like to note that the claim contains several statements that are intended use of the device, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Smith teaches all the claimed limitations discussed above however, Smith does not disclose that the suture is prevented from moving in any direction when the gripping portions are in a closed position.

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Schwartz discloses a distal body portion (20, distal portion), a proximal body portion (24) with opposed gripping portions (36 and 37) defining a suture receiving aperture (30) transverse to the longitudinal axis, a channel (22), the anchoring member includes an annular ring (distal most portion of 20 is an annular ring), a locking mechanism (36 and 37 portions that lock into each other, also disclosed are multiple teeth and grooves, one set could be the gripping portions and another set the locking mechanism), and in the open position the proximal portion is non-circular and is circular in the closed position (Fig. 9). The locking mechanism contains a male/female engagement mechanism (Fig. 9) and once the locking mechanism is closed so the gripping portion crimp the suture, the suture will be prevented from moving in any direction.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Smith with a locking mechanism that would prevent the suture from moving in any direction in view of the teachings of Schwartz in order to be able to secure the suture in the bone and maintain a tension on the suture while preventing it from being pulled out.

Claim 6: Smith discloses that the proximal body portion includes at least one channel (the portions that connect 60 to 35) angling away from the aperture to receive the suture in a recessed protected position (Fig. 2).

Claim 7: That the anchoring member comprises at least one annular ring transverse to the longitudinal axis of the distal body portion (see Fig. below) .

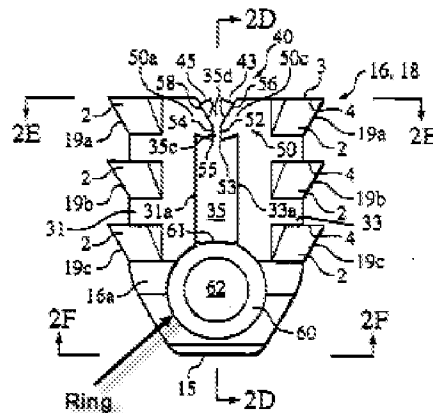


FIG. 2B

Claims 8 and 9:

Smith teaches all the claimed limitations discussed above however, Smith does not disclose a locking mechanism comprises a first portion defining a lock projection and a second portion defining a lock recess for receiving the lock projection.

Schwartz discloses a locking mechanism (36 and 37 portions that lock into each other, also disclosed are multiple teeth and grooves, one set could be the gripping portions and another set the locking mechanism) that is integrally formed (Fig. 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Smith with a locking mechanism as the one taught by Schwartz in order to be able to secure the suture in the bone.

With respect to the locking mechanism being integrally formed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the locking mechanism integral with the body, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put

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together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claim 10: The aperture is elongated longitudinally to receive at least two suture ends extending transversely and spaced longitudinally within the aperture (Fig. 2D).

Claim 11: The aperture is elongated transversely to receive at least two suture ends extending transversely and spaced longitudinally within the aperture (Fig. 2D).

Claim 12: A suture (10) wherein the suture has first and second ends, the first end being fixed to the suture anchor and the second end being receivable by the aperture in the open position to form a sliding suture loop, the second end being gripped by the aperture in the closed position to form a fixed suture loop (Fig. 1).

Response to Arguments

8. Applicant's arguments with respect to Smith reference not preventing the movement of the suture in any direction have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed March 23, 2009 have been fully considered but they are not persuasive.

Regarding the Smith reference, applicant argues that the Smith reference does not show that the transverse dimension on the anchoring member is smaller than the transverse dimension of the proximal portion. The examiner, disagrees, as explained in the rejection above, the proximal portion ends at point 4 which has a larger transverse dimension than the distal portion of 2 which is the anchoring member.

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In addition, applicant argues that the Smith reference does not have a suture transversely oriented relative to the longitudinal axis of the suture anchor, the examiner disagrees since a portion of the suture is transversely oriented in the suture anchor as seen in Fig. 2D.

10. With respect to the Schwartz reference, applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773